UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PUBLIC PENSION FUND GROUP, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**No. 4:08-CV-1859 (CEJ)**
	)	
KV PHARMACEUTICAL COMPANY, et al.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on defendants' motions to dismiss lead plaintiffs' consolidated amended complaint. Lead plaintiffs filed their opposition, and the issues are fully briefed.

I. The Parties

Lead plaintiffs are two pension plans for the public employees of Norfolk County, Massachusetts and the City of Boston. KV Pharmaceutical Company (KV) is a publicly-traded entity, which develops, manufactures, and markets prescription drug products. KV offers Class A and B common stock as well as preferred stock.

Marc S. Hermelin (Hermelin) served as KV's Chief Executive Officer (CEO) and Vice-Chair of the Board of Directors (the Board) from 1975 until August 2006. Hermelin became Chairman of the Board in August 2006.

From September 2006 through December 5, 2008, David Van Vliet (Van Vliet) served as KV's Chief Administrative Officer. Then, on December 5, 2008, Van Vliet became KV's President and interim CEO.

Since April 2007, Rita Bleser (Bleser) has served as President of KV's Pharmaceutical Manufacturing Division.

II. Factual and Procedural Background[1]

In April 2003 and January 2004, the United States Food and Drug Administration (FDA) issued KV a Form FDA 483 (the "2003 Form 483" and "2004 Form 483"). (Doc. #66, at 39, para. 104). The first page of a Form FDA 483 provides:

> **This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to [the] FDA at the address above.**

See (Doc. #66-3, at 1).

On June 14, 2004, KV filed a Form 10-K for the fiscal year ending March 31, 2004 (the "2004 Form 10-K"), announcing that:

> **All pharmaceutical manufacturers are subject to extensive regulation by the federal government, principally the FDA, and, to a lesser extent, by state, local and foreign governments. The Federal Food, Drug and Cosmetic Act, or FDCA, and other federal statutes and regulations govern or influence, among other things, the development, testing, manufacture, safety, labeling, storage, recordkeeping [sic], approval, advertising, promotion, sale, and distribution of pharmaceutical products. Pharmaceutical manufacturers are also subject to certain record keeping and reporting requirements, establishment registration and product listing, and FDA inspections**

(Doc. #66, at 38, para. 102). Additionally, KV stated that:

> **We believe that all of our facilities comply with applicable regulatory requirements. . . .**
>
> **We are currently in material compliance with [the current good manufacturing practices,] cGMP[,] and are registered with the appropriate agencies.**

(Doc. #66, at 39, para. 104). Hermelin signed the 2004 Form 10-K on behalf of KV. Id. at 11, para. 19.

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[1]**The background facts are based on the allegations in lead plaintiffs' consolidated amended complaint.**

In January 2005, the FDA issued KV a third Form FDA 483 (the "2005 Form 483"). Id. at 40, para. 105.

On June 14, 2005, KV filed a Form 10-K for the fiscal year ending March 31, 2005 (the "2005 Form 10-K"), which Hermelin signed on behalf of KV. Id. at 11, para. 19. "As in its 2004 [Form] 10-K, KV detailed the 'extensive' governmental regulation of the pharmaceutical manufacturing industry and the severe penalties for non-compliance with cGMP." Id. at 39, para. 104. In two separate sections of the 2005 Form 10-K, KV stated:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements. . . .**
>
> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.**

Id. at 39-40, para. 105.

In March 2006, the FDA issued KV a fourth Form FDA 483 (the "2006 Form 483"). Id. at 41, para. 106.

On June 14, 2006, KV filed a Form 10-K for the fiscal year ending March 31, 2006 (the "2006 Form 10-K") and reported:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements. . . .**
>
> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.**

(Doc. #66, at 40, para. 106). Hermelin signed the 2006 Form 10-K on behalf of KV. Id. at 11, para. 19.

In April 2007, the FDA issued KV a fifth Form FDA 483 (the "2007 Form FDA 483"). (Doc. #66, at 44, para. 111).

On July 26, 2007, KV launched its generic version of the cardiovascular drug Toprol XL, Metoprolol Succinate Extended Release Tablets ("Generic Metoprolol"),

whose sales exceeded $100 million in the first year. Id. at 8-9, para. 10. On November 2007, KV announced record revenues of $175.4 million for the second quarter fiscal year 2008 as compared to $108.8 million for the same quarter in the previous year. Id. at 24-25, para. 63. Generic Metoprolol contributed $50 million to KV's financial increase. On February 15, 2008, KV announced revenues of $164 million for the next quarter, a thirty-nine percent (39%) increase. Id.

In its November 20, 2007 press release, KV announced its second quarter fiscal 2008 results:

> **Net revenues for the second quarter increased 61% to $175.4 million, compared to $108.8 million for the second quarter of fiscal [year] 2007, with the Company's ETHEX generic/non-branded subsidiary reporting net revenue growth of 102% to $118.4 million.**
>
> *** * * ***
>
> **The improvement in net revenues was due to the July 2007 launch of the Company's generic alternative to the 100mg and 200mg strengths of AstraZeneca's Toprol-XL(R), Metoprolol Succinate Extended Release Tablets and to continued growth of higher margin branded products in the existing product lines. Net revenue contribution from Metoprolol Succinate Extended Release Tablets during the second quarter of fiscal [year] 2008, which including launch quantities, was $50.4 million.**

Id. at 41-42, para. 107.

> **In its February 15, 2008 press release, KV explained that:**
>
> **Net revenues in [the third quarter for fiscal [year] 2008, ending December 31, 2007] are estimated to be $163.6 million, up 38.7% from fiscal [year] 2007 third quarter net revenues.**
>
> *** * * * ***
>
> **ETHEX Corporation, KV's generic/non-branded business contributed approximately $102.1 million of revenue, up 57.7% from the prior-year quarter, primarily due to sales of 100mg and 200mg strengths of metoprolol succinate extended release tablets launched in the second quarter of fiscal [year] 2008. ETHEX comprises 62.4% of KV's total revenue for the third quarter period.**

(Doc. #66, at 42-43, para. 109).

In March 2008, the FDA issued KV a fifth Form FDA 483 (the "2008 Form 483"). Id. at 45, para. 114. On March 26, 2008, KV filed its Form 10-K for the fiscal year ending on March 31, 2007 (the "2007 Form 10-K"), "disclos[ing] that[,] on March 13, 2008, [the] FDA and the Missouri Department of Health and Senior Services ("MDHSS") had placed a 'hold' on KV's inventory of 'unapproved products' worth approximately $39 million in annual sales. The products consisted of cough and cold[-]related medicines containing immediate[-]release guaifenesin." Id. at 26, para. 67. Additionally, KV stated:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements. . . .**
>
> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.**

Id. at 43, para. 111.

On May 29, 2008, the price of KV's Class A stock dropped from $26.15 to $25.01 per share, and the price of KV's Class B stock fell from $118.125 to $113.375 per share. Id. at 52, para. 134(d)-(e).

The next day, KV filed a Form 12b-25 (the "2008 Form 12b-25") to report its preliminary results for the fourth quarter . . . fiscal [year] 2008, ending March 31, 2008, wherein KV stated:

> **[T]he Company estimates that net revenues for fiscal [year] 2008 will increase $158.8 million, or 35.8%, to $602.5 million due primarily to sales growth of 56.4% experienced in its specialty generics/non-branded products segment. The increase in specialty generic net revenues resulted primarily from the launch in July 2007 of the 100mg and 200mg strengths of metoprolol succinate extended-release tablets, which generated estimated net revenues of $119.1 million in [the] fiscal [year] 2008.**

(Doc. #66, at 44, para. 112).

On June 13, 2008, the price for KV's (1) Class A common stock dropped from $19.05 to $18.49 per share; (2) Class B common stock fell from $19.05 to $18.34 per share; and (3) preferred stock dropped from $96.5375 to $94.750 per share. Id. at 53, para. 135(b)-(d).

On June 26, 2008, KV filed a Form 10-K for the fiscal year ending March 31, 2009 (the "2008 Form 10-K"). "As in its four prior 10-Ks, KV detailed the 'extensive' governmental regulation of the pharmaceutical manufacturing industry and the severe penalties for non-compliance. In two separate sections of the 2008 10-K, KV stated:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements. . . .**
>
> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.**

Id. at 45, para. 114.

In its August 11, 2008 Form 8-K (the "2008 Form 8-K"), KV reported:

> **Net revenues for the first quarter [of the fiscal year 2009] increased 30.2%, or $34.5 million, to $148.9 million, compared with $114.4 million in the first quarter of fiscal [year] 2008. . . . Revenue growth during the quarter was impacted by: . . . . . [sic] a net sales gain of 52.6% over the prior year period at the Company's ETHEX generic/non-branded marketing subsidiary, contributed to by sales of 25mg, 50mg, 100mg, and 200mg strengths of metoprolol. . . .**
>
> **At the close of the first quarter of fiscal [year] 2009, due to higher-than-expected demand from our customers for certain generic products, the Company had an unusually large volume of unshipped open orders for generic products, representing approximately $10 million of net revenues.**

(Doc. #66, at 46, para. 115, 117). KV also announced that the audit committee of the Board had commenced an independent investigation into allegations of management misconduct. Id. at 6, para. 3.

On August 12, 2008, the stock price for KV's (1) Class A common stock closed at $21.42, falling $0.94 per share from its previous day's close of $22.36 per share;

(2) Class B common stock closed at $21.35, falling nearly $1.00 per share from its previous day's close of $22.34 per share; and (3) preferred stock closed at $101.125, falling $3.25 per share from its previous day's close of $104.375 per share. Id. at 54, para. 136(c)-(e).

In its November 12, 2008 quarterly earnings report, KV admitted that the scope and seriousness of the investigation had expanded. Id. at 30, para. 80. The management misconduct at issue was linked to the FDA regulations and other compliance matters. Id.

On November 13, 2008, the stock price for KV's (1) Class A common stock closed at $5.90, falling $8.36 per share from its previous close of $14.26; (2) Class B common stock closed at $5.875, falling $8.385 per share from its previous close of $14.26; and (3) preferred stock closed at $44.25, falling $30.25 per share from its previous close of $74.50. Id. at 55, para. 136(d)-(f).

On December 2, 2008, Joseph Mas filed a class-action complaint against KV and its executive officers on behalf of purchasers of KV securities between February 15, 2008 and November 12, 2008, alleging that KV and several of KV's executives had issued materially false and misleading statements, regarding KV's compliance with federal regulations that govern the manufacture and marketing of certain generic drug products containing guaifenesin as well as KV's current and future financial prospects. See Public Pension Fund Group v. KV Pharm. Co., et al., No. 4:08-CV-1859 (CEJ).

On December 5, 2008, KV terminated Hermelin "for cause." (Doc. #66, at 34, para. 87). Hermelin's employment agreement including the following clause:

> **Employer may terminate [the] Agreement at any time for Cause. For purposes of [the] Agreement, "Cause" shall mean that (i) Employee has committed a breach of a fiduciary duty, embezzlement, larceny, or has willfully failed to perform his duties to Employer, and in doing so has**

> **acted with full knowledge of all pertinent facts; and (ii) such act has had a material and demonstrable adverse effect on Employer.**

Id. at 34-35, para. 89 (emphasis in original) (footnote omitted). Hermelin remains a member of the Board, and he owns 10.5% of the Class A shares and 66% of the Class B shares, which represents a controlling share of KV's stock. Id. at 34, para. 87.

On December 22, 2008, the stock price for KV's (1) Class A common stock closed at $2.71, falling $2.68 per share from its previous close of $5.39; (2) Class B common stock closed at $2.82, falling $2.53 per share from its previous close of $5.35; and (3) preferred stock closed at $33.15, falling $8.10 per share from its previous close of $41.25. Id. at 56, para. 136(a), (c).

On December 23, 3008, KV announced that it was suspending the manufacture and distribution of its pharmaceutical products in tablet form, which represented $159 million of its net revenues in the 2008 fiscal year. Id. at 7, para. 6. In addition, KV admitted that this operations decision would have a materially adverse effect on its financial position. Id.

On December 24, 2008, KV's (1) Class A common stock fell from $2.71 to $1.99 per share; and (2) Class B common stock fell from $2.82 to $2.18 per share. (Doc. #66, at 56, para. 136(b)).

On January 9, 2009, Herman Unvericht filed a class-action complaint against KV and its executive officers on behalf of purchasers of KV securities between February 15, 2008 and November 12, 2008, claiming violations of the federal securities laws. See Herman Unvericht v. KV Pharm. Co., et al., No. 4:09-CV-61 (CEJ). Then, on January 21, 2009, Norfolk County Retirement System filed a class-action complaint against KV and its executive officers on behalf of purchasers of KV securities between May 31, 2007 and November 12, 2008, claiming violations of the federal securities

laws. See Norfolk County Ret. Sys. v. KV Pharm. Co., et al., No. 4:09-CV-138 (CEJ).

In its January 26, 2009 press release, KV announced that (1) it had suspended all of its manufacturing activities; (2) it had recalled most of its products; and (3) the FDA's Office of Criminal Investigations had opened an investigation into the management misconduct. (Doc. #66, at 7, para. 6). On that same day, KV's (1) Class A common stock dropped from $2.13 to $0.51; (2) Class B common stock dropped from $2.25 to $0.58; and (3) preferred stock dropped from $34.875 to $23.50. Id. at 57, para. 136(a)-(c).

On February 2, 2009, the FDA inspectors issued KV a Form FDA 483 (the "2009 Form 483") based on the inspections that occurred between December 15, 2008 and February 2, 2009. (Doc. #66-3). In the 2009 Form 483, the FDA reported that thirty-five observations, regarding KV's (1) quality system; (2) packaging and labeling; (3) facilities and equipment system; (4) laboratory system; (5) material system; and (6) production system. Id.

On March 2, 2009, the United States filed a Complaint for Permanent Injunction (the "FDA Complaint") against several defendants, including KV, Hermelin, Van Vliet, and Bleser. See U.S. v. KV Pharm. Co., et al., No. 4:09-CV-334 (RWS), seeking to permanently enjoin KV and its agents from manufacturing, packaging, labeling, holding, and/or distributing any of its products, and alleging, *inter alia*, that:

> **13. The [FDA's] inspections of Defendant KV[']s facilities have established that the drugs manufactured by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of KV drugs and components are not in compliance with CGMP. See 21 U.S.C. § 351 (a)(2)(B); 21 C.F.R. Parts 210 and 211. . . .**
>
> **15. During [the] FDA's most recent inspection of Defendant KV's facilities between December 15, 2008 and February 2, 2009 (the "February 2009 inspection"), FDA investigators documented thirty-five**

(35) separate deviations from CGMP. These CGMP violations include, but are not limited to, the following:

A. Failure to follow the responsibilities and procedures applicable to the quality control unit, as required by 21 C.F.R. § 211.22(d);

B. Failure to establish control procedures to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug market, as required by 21 C.F.R. § 211.110(a);

C. Failure to make written records of investigations into unexplained discrepancies and the failure to make written records of investigations of a batch or any of its components to meet specifications, as required by 21 C.F.R. § 211.192;

D. Failure to review and approve drug product production and control records by the quality control unit to determine compliance with all established, approved written procedures before a batch is relased or distributed, as required by 21 C.F.R. § 211.192;

E. Failure to review and approve changes to written procedures by the quality control unit, as required by 21 C.F.R. § 211.100(a);

F. Failure to clean, maintain, and sanitize equipment and utensils at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product, as required by 21 C.F.R. § 211.67 (a); and

G. Failure to follow written production and process control procedures in the execution of production and process control functions, as required by 21 C.F.R. § 211.100(b). . . .

18. [The] FDA's February 2009 inspection revealed that certain . . . drugs manufactured and distributed by Defendants lacked new drug applications ("NDAs") or approved abbreviated new drug applications ("ANDAs"), as required by 21 U.S.C. § 355, and are not exempt under 21 U.S.C. § 355(i) from the [Security and Exchange] Act's pre-market approval requirements. As a result, these drugs are unapproved new drugs within the meaning of 21 U.S.C. § 355(a). . . .

20. [The] FDA's February 2009 inspection also revealed that certain . . . drugs are misbranded because they are unapproved new drugs and they lack scientific evidence to demonstrate that they are safe and effective as indicated in their directions for use. Such drugs do not bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), and they are not exempt from this requirement pursuant to 21 C.F.R. §§ 201.115 or 201.100. . . .

23. Defendant KV Pharmaceutical Company has a history of continuing CGMP violations. The deficiencies observed by [the] FDA[,] at the most recent inspection in February 2009, are the same as, or similar to, prior violations observed by [the] FDA at several other inspections conducted during the last eight years.

24. Defendant's noncompliance has continued despite repeated warnings from the FDA regarding its CGMP violations. At the conclusion of each FDA inspection in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008, and 2/2009, FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to Defendants, notifying them of the investigators' observations. The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants, who expressed a desire to correct the deficiencies. Nevertheless, [the] FDA investigators have continued to observe CGMP violations at subsequent inspections.

25. [The] FDA also issued a Warning Letter to Defendant KV Pharmaceutical Company on May 9, 2000, identifying numerous CGMP violations found during the February/March 2000 inspection. The Warning Letter emphasized the serious nature of the CGMP violations . . . and stated that a failure to correct the violations could lead to regulatory actions, including seizure and/or injunction.

26. On October 11, 2002, [the] FDA issued a Warning Letter to Defendant KV Pharmaceutical Company for marketing unapproved new drugs in violation of 21 U.S.C. § 355.

(Doc. #66-2, at 6-12).

Additionally, on March 2, 2009, the Government and several individuals, including KV, Hermelin, Van Vliet, and Bleser entered into a Consent Decree of Permanent Injunction (the "Consent Decree"). See (Doc. #66-4). The Consent Decree indicates that each of the named defendants signed the agreement, "while disclaiming any liability in connection therewith, . . . and without admitting or denying the allegations in the [FDA] Complaint." Id. at 3. In paragraph (5)(J) of the Consent Decree, the parties agree, *inter alia*, that:

Defendants [shall] report to [the] FDA in writing the actions taken to:

(1) Correct the CGMP deviations brought to Defendants' attention by [the] FDA since January 1, 2005, the CGMP expert, and any other source

including, but not limited to, any experts hired prior to the entry of this Decree; and

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP.

Id. at 9-10.

In a Memorandum and Order dated April 15, 2009, the Court, *inter alia*, consolidated the three securities class actions and appointed the Public Pension Fund Group as lead plaintiffs.[2] Then, on May 22, 2009, lead plaintiffs filed their consolidated amended complaint against defendants KV, Hermelin, Van Vliet, and Bleser (collectively, "the defendants"), alleging that the defendants violated § 10(b) of the Securities Exchange Act (the "Act") and the Securities Exchange Commission ("SEC") Rule 10b-5(a)-(c) between June 15, 2004 and January 23, 2009 (the "class period"). Subsequently, the defendants filed separate motions to dismiss lead plaintiffs' consolidated amended complaint.

III. Legal Standard

The purpose of a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure is to test the legal sufficiency of the complaint. The factual allegations of a complaint are assumed true and construed in favor of the plaintiff, "even if it strikes a savvy judge that actual proof of those facts is improbable." Bell Atlantic Corp. v. Twombly, --- U.S. ---, 127 S. Ct. 1955, 1965 (May 21, 2007) citing Swierkiewicz v. Sorema N.A., 534 U.S. 506, 508 n.1 (2002); Neitzke v. Williams, 490 U.S. 319, 327 (1989) ("Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations"); Scheuer v. Rhodes, 416 U.S.

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[2]The Public Pension Fund Group includes the State-Boston Retirement System and the Norfolk County Retirement System. See (Doc. #66, at 6).

232, 236 (1974) (a well-pleaded complaint may proceed even if it appears "that a recovery is very remote and unlikely"). The issue is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of his claim. Id. A viable complaint must include "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp., 127 S. Ct. at 1974. See also id. at 1969 ("no set of facts" language in Conley v. Gibson, 355 U.S. 41, 45-46 (1957), "has earned its retirement."). "Factual allegations must be enough to raise a right to relief above the speculative level." Id. at 1965.

IV. Discussion

Lead plaintiff filed a three-count consolidated amended complaint. In Count I, lead plaintiffs claim that KV and Hermelin violated § 10(b) of the Act and SEC Rule 10b-5(a)-(c). In Count II, they assert that Van Vliet and Bleser violated § 10(b)and Rule 10b-5(a)-(c). In Count III, lead plaintiffs allege that each of the individual defendants, Hermelin, Van Vliet, and Bleser, violated § 20(a) of the Act. The Court will address the claims against each defendant in turn.

Rule 9(b) provides that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed.R.Civ.P. 9(b). With respect to securities fraud claims, the Private Securities Litigation Reform Act of 1995 ("PSLRA") "dictates a modified analysis due to its special heightened pleading rules." Kushner v. Beverly Enters., Inc., 317 F.3d 820, 824 (8th Cir. 2003). The heightened pleading standard is intended to eliminate abusive securities litigation and put an end to the practice of pleading "fraud by hindsight." *In re* K-Tel Int'l, Inc. Sec. Litig., 300 F.3d 881, 889 (8th Cir. 2002).

The PSLRA requires plaintiffs "to specify each misleading statement or omission and specify why the statement or omission was misleading." Kushner, 317 F.3d at 826

(citing 15 U.S.C. § 78u-4(b)(1)). The complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78-4(b)(2); see also Kushner, 317 F.3d at 826 (citation omitted). In evaluating this information, the PSLRA requires the Court to consider plausible opposing inferences. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 310, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007). Finally, the Court must "disregard 'catch-all' or 'blanket' assertions that do not live up to the particularity requirements." Kushner, 317 F.3d at 824 (quoting Fla. State Bd. of Admin. v. Green Tree Fin. Corp., 270 F.3d 645, 660 (8th Cir. 2001)).

A. Lead Plaintiffs' Section 10(b) and Rule 10b-5(b) Claims

"Section 10(b) and Rule 10b-5 prohibit fraudulent conduct in the sale and purchase of securities." McAdams v. McCord, 584 F.3d 1111, 1113 (8th Cir. 2009), citing 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5. "To state a private securities fraud claim under Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5[(b)], a plaintiff must allege: '(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as 'transaction causation'; (5) economic loss; and (6) 'loss causation,' *i.e.*, a causal connection between the material misrepresentation and the loss.'" Horizon Asset Mgmt. Inc. v. H&R Block, Inc., 580 F.3d 755, 760 (8th Cir. 2009) (citations omitted).

1. Section 10(b) and Rule 10b-5(b) Claims Against KV and Hermelin

Lead plaintiffs allege that KV and Hermelin, KV's CEO from 1975 until August 2006, made materially false and misleading statements and omissions in violation of § 10(b) and Rule 10b-5(a).

a. The Alleged Misrepresentation Regarding KV's Compliance

Lead plaintiffs note that, on June 14, 2004, KV issued the 2004 Form 10-K which Hermelin signed, which included the following statements:

> **We believe that all of our facilities comply with applicable regulatory requirements. . . .**
>
> **We are currently in material compliance with cGMP and are registered with the appropriate agencies.**

(Doc. #66, at 39, para. 104). Lead plaintiffs allege that these statements were false and misleading because, when KV filed the 2004 Form 10-K, both KV and Hermelin knew, but failed to disclose, the "violations" listed in the 2003 Form 483 and the 2004 Form 483. (Doc. #66, at 39, para. 104).

Lead plaintiffs also claim that the compliance statements in the Form 10-Ks that KV filed in 2005, 2006, 2007, and 2008 were false and misleading. Each of the Form 10-Ks included the following two statements:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements. . . .**
>
> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.**

(Doc. #66, at 40-41, 43-46, para. 105-6, 111, 114). Lead plaintiffs assert that: (1) the 2005 10-K was false and misleading because KV and Hermelin knew, but failed to disclose, the 2005 Form 483 that the FDA issued KV in January 2005, which contained "'the same as, or similar . . . prior violations' [as] contained in the 2003 Form 483 and the 2004 Form 483"; (2) the 2006 10-K was false and misleading because KV and Hermelin knew, but failed to disclose, the 2006 Form 483 that the FDA issued KV in March 2006, which contained "'the same as, or similar . . . prior violations' [as] contained in the 2003 Form 483, the 2004 Form 483, and 2005 Form 483"; (3) the 2007 10-K was false and misleading because KV and Hermelin knew, but failed to

disclose, the 2007 Form 483 that the FDA issued KV in April 2007, which contained "'the same as, or similar . . . prior violations' [as] contained in the 2003 Form 483, the 2004 Form 483, 2005 Form 483, and 2006 Form 483"; and (4) the 2008 10-K was false and misleading because KV and Hermelin knew, but failed to disclose, the 2008 Form 483 that the FDA issued KV in March 2008, which contained "'the same as, or similar . . . prior violations' [as] contained in the 2003 Form 483, the 2004 Form 483, 2005 Form 483, 2006 Form 483, and 2007 Form 483[.]" Id.

Upon careful review , the Court concludes that lead plaintiffs have failed to allege with sufficient particularity that the compliance statements in the Form 10-K that the FDA issued to KV in 2004, 2005, 2006, 2007, and 2008 were false and misleading. The first page of every Form FDA 483 states that the "document lists observations made by the FDA representative(s) during the inspection[, and that t]hey are inspectional observations, and do not represent a final determination regarding [a company's] compliance." (Doc. #66-3) (emphasis added). Furthermore, the FDA recognized the "misuse of and concerns with the [Form 483,]" and added this clarifying language to resolve any "perceived ambiguity [that might] result in inaccurate conclusions about the compliance of an inspected firm." See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/ucm072012.htm (last visited Feb. 10, 2010). Thus, the Form 483s issued to KV only contained observations—not "a list of cGMP violations" as alleged by lead plaintiffs. In fact, lead plaintiffs cite to the March 2, 2009 FDA Complaint against the defendants in this action, wherein the FDA alleges that the Form 483s contained "a detailed List of Inspectional Observations[.]" (Doc. #66, at 16-17, para. 38). In their complaint, the FDA refers to the observations listed in the 2004, 2005, 2006, 2007, and 2008 Form 483s as

"violations." (Doc. #66-2, at 9, para. 24). However, as stated above, the FDA explicitly states on its website that a Form 483 does not represent the FDA's final determination of a company's compliance. In fact, the FDA in the Consent Decree characterizes the observations in the Form 483s as only "deviations." See (Doc. #66-4, at 9, para. (5)(J)). Even assuming the observations listed in the Form 483s indicate that KV was not in material compliance at the time KV filed the five Form 10-Ks, lead plaintiffs plead no specific facts that show that KV was not in compliance when KV filed each of the Form 10-Ks.

Lead plaintiffs also argue that the Consent Decree "constitutes an admission by [KV] that [it] knew [that it] had been violation cGMP since at least January 1, 2005." (Doc. #109, at 21). As stated above, the FDA referred to the observations as "deviations"—not violations. Moreover, KV signed the Consent Agreement "without admitting or denying the allegations" in the agreement. (Doc. #66-4, at 3).

Therefore, based on the foregoing,[3] the Court finds that lead plaintiffs have failed to plead with sufficient particularity that the compliance statements were misrepresentations.

b. The Alleged Misrepresentations Regarding KV's Financial Status

In addition to the compliance statements, lead plaintiffs allege that KV made four false and misleading statements regarding KV's financial performance.

On November 20, 2007, KV issued a press release, reporting:

> **Net revenues for the second quarter increased 61% to $175.4 million, compared to $108.8 million for the second quarter of fiscal [year] 2007, with the Company's ETHEX generic/non-branded subsidiary reporting net revenue growth of 102% to $118.4 million**

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[3]Lead plaintiffs allege that, "[o]n May 9, 2009, [the] FDA issued a Warning Letter to KV identifying numerous cGMP violations during a February and March 2009 inspection." (Doc. #66, at 17, para. 39). The FDA issued this warning letter outside the asserted class period: June 15, 2004 through January 23, 2009. Id. at 6, para. 1.

*** * * ***

The improvement in net revenues was due to the July 2007 launch of the Company's generic alternative to the 100mg and 200mg strengths of AstraZeneca's Toprol-XL(R), Metoprolol Succinate Extended Release Tablets and to continued growth of higher margin branded products in the existing product lines. Net revenue contribution from Metoprolol Succinate Extended Release Tablets during the second quarter of fiscal

[year] 2008, which including launch quantities, was $50.4 million.

(Doc. #66, at 41-42, para. 107).

Then, the February 15, 2008 press release stated that:

[KV's n]et revenues in [the third quarter for fiscal [year] 2008, ending December 31, 2007] are estimated to be $163.6 million, up 38.7% from fiscal [year] 2007 third quarter net revenues.

*** * * * ***

ETHEX Corporation, KV's generic/non-branded business contributed approximately $102.1 million of revenue, up 57.7% from the prior-year quarter, primarily due to sales of 100mg and 200mg strengths of metoprolol succinate extended release tablets launched in the second quarter of fiscal [year] 2008. ETHEX comprises 62.4% of KV's total revenue for the third quarter period.

Id. at 42-43, para. 109.

On May 30, 2008, KV filed its 2008 Form 12-25 and reported:

[T]he Company estimates that net revenues for fiscal [year] 2008 will increase $158.8 million, or 35.8%, to $602.5 million due primarily to sales growth of 56.4% experienced in its specialty generics/non-branded products segment. The increase in specialty generic net revenues resulted primarily from the launch in July 2007 of the 100mg and 200mg strengths of metoprolol succinate extended-release tablets, which generated [an] estimated net revenues of $119.1 million in [the] fiscal [year] 2008.

Id. at 44, para. 112.

In its 2008 Form 8-K dated August 11, 2008, KV reported:

Net revenues for the first quarter [of the fiscal year 2009] increased 30.2%, or $34.5 million, to $148.9 million, compared with $114.4 million in the first quarter of fiscal [year] 2008. . . . . [sic] Revenue growth

> **during the quarter was impacted by: . . . . . [sic] a net sales gain of 52.6% over the prior year period at the Company's ETHEX generic/non-branded marketing subsidiary, contributed to by sales of 25mg, 50mg, 100mg, and 200mg strengths of metoprolol.**

Id. at 46, para. 116.

Lead plaintiffs allege that these financial statements were false and misleading because KV and Hermelin knew, but failed to disclose, "that, according to the Form 483 issued by [the] FDA on February 2, 2009, KV's manufacturing process for Generic Metoprolol violated [the] FDA regulations, including cGMP[.]" (Doc. #66, at 42, para. 108; 44, para. 113; 46-47, para. 116-17). Additionally, lead plaintiffs argue that KV and Hermelin had a duty to disclose these manufacturing issues with the generic metoprolol. (Doc. #109, at 50).

The Eighth Circuit holds that "[a] duty [to disclose] arises . . . if there have been inaccurate, incomplete or misleading disclosures." K-Tel, 300 F.3d 881, 898. "However, the requirement is not to dump all known information with every public announcement, but the law requires 'an actor to provide complete and non-misleading information with respect to the subjects *on which he undertakes to speak*.'" Id. (emphasis in original) (internal quotations and citations omitted).

Here, through the statements in the 2007 and 2008 press releases, 2008 Form 12-25, and 2008 8-K, KV only reported its financial performance. KV did not attribute its financial success to its outstanding manufacturing processes or quality control measures associated with the production of the generic metoprolol. Moreover, the financial statements did not discuss KV compliance with the FDA regulations. Because KV chose only to speak about the financial status of the company, KV was "not required to dump all known information" about its manufacturing and regulatory

issues. Moreover, lead plaintiffs do not allege that the figures reported in the financial statements were false and misleading.

Additionally, the cases cited by lead plaintiffs are nonpersuasive and distinguishable from this action because those cases involve withholding information closely-related to the company's public statements. See Schultz v. Applica Inc., 488 F.Supp.2d 1219, 1224-26 (S.D. Fla. 2007) (company issued financial statements without disclosing its GAAP violations and new product defects and slow sales); *In re* Immune Response Sec. Litig., 375 F.Supp.2d 983, 1019 (S.D. Cal. 2005) (company issued positive statements that a drug used for treatment of HIV without disclosing negative clinical results); *In re* Unumprovident Corp. Sec. Litig., 396 F.Supp.2d 858, 885-92 (E.D. Tenn. 2005) (company issued financial statements without disclosing its (1) improper practice of denying claims and recognizing it as income in its financial statements and (2) GAAP violations); *In re* Van der Moolen Holding N.V. Sec. Litig., 405 F.Supp.2d 388, 392, 397 (S.D.N.Y. 2005) (company issued financial statements without disclosing true sources of its revenue); Anderson v. Abbott Labs., 140 F.Supp.2d 894, 906 (N.D. Ill. 2001) (distinguishing Grossman v. Waste Mgmt. Inc., 589 F.Supp. 395 (N.D. Ill. 1984), where company released a press release, "tout[ing] its environmental record," but failed to disclose its potential regulatory violations).

Based on the foregoing, the Court concludes that lead plaintiffs have failed to allege with sufficient particularity that the financial statements in KV's 2007 and 2008 press releases, 2008 Form 12-25, and 2008 8-K were misrepresentations.

Lead plaintiffs also claim that a second statement in the 2008 Form 8-K was false and misleading, where KV reported that:

> **At the close of the first quarter of fiscal [year] 2009, due to higher-than-expected demand from our customers for certain generic products, the Company had an unusually large volume of unshipped open orders for**

> **generic products, representing approximately $10 million of net revenues.**

(Doc. #66, at 46, para. 117). Lead plaintiffs allege that this statement is a misrepresentation "because [d]efendants knew, and failed to disclose, that [its] manufacturing disruptions and inefficiencies, as well as violations of [the] FDA regulations and cGMP, were resulting in a material backlog of unshipped customer orders." Id. at 47, para. 118.

The Court finds that this conclusory allegation fails to meet the heightened pleading standards set forth in Rule 9(b), Fed.R.Civ.P., and the PSLRA. Lead plaintiffs argue that this statement is false and misleading because the sales reported in the statement "should have occurred in the next quarter." (Doc. #109, at 53). Additionally, lead plaintiffs claim that the next quarter KV "admitted that the $10 million of unsold generic product had not been the result of unmet strong customer demand, but was in fact caused by manufacturing inefficiencies and product recalls." Id. However, KV reported in the Form 12b-25 filed on November 12, 2008:

> **[W]e had unshipped open orders of generic products at the close of the second quarter of 2009 that approximated $18.0 million of net revenues. These unshipped orders resulted primarily from higher-than-expected demand from our customers for metoprolol and manufacturing interruptions and inefficiencies that resulted in abnormally low production during the [second] quarter.**

(Doc. #96-4, at 38). This statement does not suggest that "anything other than high customer demand" caused the backlog in the first quarter. (Doc. #111, at 23). Lead plaintiffs provide no other facts to support its contention. As such, the Court finds that lead plaintiffs have failed to plead with sufficient particularity that the second statement in KV's 2008 Form 8-K constitutes a misrepresentation.

c. The Alleged Omissions

Lastly, lead plaintiffs allege that KV and Hermelin failed to disclose the eight Form 483s that the FDA issued to KV in 2003 through 2008. KV and Hermelin contend that they "had no duty to disclose the existence of the 483 Reports [because] the information contained in the Reports was not material as a matter of law[,] and, . . . that information was already public and available to the reasonable investor." (Doc. #96, at 30).

In B.L. Sailors, the Eighth Circuit held that "[t]he securities laws require disclosure of information *that is not otherwise* in the public domain." 4 F.3d 610, 612 (8th Cir. 1993) (emphasis in original) (citations omitted). The court further explained that "Rule 10b-5 does not protect 'nondisclosed facts equally known *or available* to both parties.'" Id. The FDA requires that:

> **All Food and Drug Administrations records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD[A] 483 and FD-2275 furnished to companies after factory inspection, and similar records.**

21 C.F.R. § 20.101(a) (emphasis added). In accordance with 21 C.F.R. § 20.101(a), an individual or company may request FDA records, including Form 483s, by submitting a request in writing. See http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm;http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm (last visited Feb. 12, 2010). Because the Form 483s that the FDA issued to KV from 2003 through 2008 were readily accessible to the public by submitting a request to the FDA, the Court finds that KV and Hermelin were under no duty to disclose these documents.

Because lead plaintiffs failed to allege with sufficient particularity that KV and Hermelin made misrepresentations and omissions in the statements regarding KV's compliance and financial performance, the Court will dismiss lead plaintiffs' claims under § 10(b) and Rule 10b-5 against KV and Hermelin.

2. Lead Plaintiffs' Section 10(b) Claim Against Van Vliet

Lead plaintiffs also allege that Van Vliet violated § 10(b). The Eighth Circuit holds that "any defendant who does not make or affirmatively cause to be made a fraudulent misstatement or omission, or who does not directly engage in manipulative securities trading practices, is at most guilty of aiding and abetting and cannot be held liable under § 10(b) or any subpart of Rule 10b-5. *In re* Charter Commc'ns, Inc., Sec. Litig., 443 F.3d 987, 993 (8th Cir. 2006).

In their consolidated amended complaint, lead plaintiffs allege that Van Vliet was aware of "material adverse information . . . but [failed to] disclose [such information] in public statements." (Doc. #66, at 65, para. 168). Lead plaintiffs provide a detailed list of false and misleading statements and omissions made by KV; however, they do not offer any facts to show that Van Vliet also made misrepresentations or omissions. As such, under Charter, the Court finds that, at most, lead plaintiffs can assert an aiding and abetting claim against Van Vliet. Because lead plaintiffs have failed to allege with sufficient particularity that Van Vliet made a misrepresentation or omission, the Court will dismiss lead plaintiffs' § 10(b) claim against Van Vliet.

3. Lead Plaintiffs' Section 10(b) Claim Against Bleser

Bleser argues that lead plaintiffs have failed to allege any facts to establish that she made any of the alleged misrepresentations and omissions, or engaged in any manipulative trading practices. In fact, lead plaintiffs admit in their response brief that they "[did] not allege that [Bleser] made any false and misleading statements." (Doc.

#109, at 72). Because lead plaintiffs have failed to allege sufficient facts to satisfy the first element of a § 10(b) claim—a material misrepresentation or omission, the Court will dismiss lead plaintiffs' § 10(b) claim against Bleser.

B. Lead Plaintiffs' Rule 10b-5(a) and (c) Claims

Rule 10b-5(a) prohibits "any device, scheme or artifice to defraud." 17 C.F.R. § 240.10b-5(a). Similarly, Rule 10b-5(c) prohibits "any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." 17 C.F.R. § 240.10b-5(c). To support their contentions, the parties rely on *In re* Able Labs. Sec. Inc., Civil Action No. 05-2681 (JAG), 2008 WL 1967509 (D.N.J. Mar. 24, 2008), and *In re* Alstom SA Sec. Litig., 406 F.Supp.2d 433 (S.D.N.Y. 2005).

The Alstom court noted that "[c]ourts have held that a plaintiff may not cast claims of misrepresentations as claims under Rule 10b-5(a) and (c) and thus evade the pleading requirement imposed in misrepresentation cases." 406 F.Supp.2d at 475. The court held that:

> Nonetheless, it is possible for liability to arise under both subsection (b) and subsections (a) and (c) of Rule 10b-5 out of the same set of facts, where the plaintiffs allege both that the defendants made misrepresentations in violations of Rule 10b-5(b), as well as that the defendants undertook a deceptive scheme or course of conduct that went beyond the misrepresentations. The subsections provide alternate mechanisms of pleading a primary violation of Section 10(b). Thus, even if a defendant who did not make any statements in connection with a particular fraud may not be held liable for fraudulent misrepresentations under subsection (b), that defendant may still be held liable under subsections (a) and (c) if it is alleged that they participated in a scheme that encompassed conduct beyond misrepresentations.

406 F.Supp.2d at 475 (emphasis added).

Similarly, in Able Labs., the district court stated that, "[w]hile Rule 10b-5(b) addresses liability for material misstatements or omissions, 'Rules 10b-5(a) and (c) encompasses conduct beyond violations.'" 2008 WL 1967509, *18 (citation omitted).

The court further explained that Rule 9(b), Fed.R.Civ.P., requires a plaintiff to specifically plead "'what manipulative acts were performed, which defendants performed them, when the manipulative acts were performed and what effect the scheme had on the securities.'" Id. at *19.

1. Lead Plaintiffs' Rule 10b-5(a) and (c) Claims Against KV and Hermelin

In their amended consolidated complaint, lead plaintiffs allege that:

> **Defendants KV and Hermelin initiated and pursued a scheme and course of conduct which concealed (i) that the Company was in consistent violation of FDA regulations and cGMP, and (ii) the Forms 483 issued to the Company by [the] FDA, in an effort to maintain an artificially high price for the Company's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. . . .**
>
> **In committing the wrongful acts alleged herein, Defendants KV and Hermelin have pursued or joined in the pursuit of a common course of conduct and acted in concert with one another in furtherance of their common plan. This conduct or scheme was designed to and did: (i) conceal that KV was in violation of FDA regulations, including cGMP, and the Forms 483 issued by FDA before and during the Class Period; (ii) maintain Hermelin's executive and directorial positions at KV and the profits, power and prestige Hermelin enjoyed as a result; and (iii) deceive the public, including the securities holders of KV, regarding the Company's business and prospects.**
>
> **Defendants KV and Hermelin accomplished their common enterprise and/or common course of conduct by causing the Company to purposefully violate FDA regulations, including cGMP, conceal the Forms 483, and make false and misleading statements about KV's compliance with [the] FDA and cGMP regulations and requirements.**

(Doc. #66, at 60, para. 148; 62-63, para. 158-59).

The Court believes that lead plaintiffs have failed to plead sufficient facts to establish that KV and Hermelin engaged in a scheme or course of conduct beyond the alleged misrepresentations and omissions. In paragraphs 148 and 159, lead plaintiffs specifically allege that KV and Hermelin's scheme consisted of failing to disclose KV's

alleged violations with cGMP and the FDA regulations and the Form 483s that the FDA issued to KV. However, in paragraph 158, lead plaintiffs present a circular argument, wherein they claim that the alleged scheme caused, *inter alia*, KV and Hermelin to conceal KV's alleged non-compliance and the Form 483s. A careful review of these allegations clearly indicates that the "scheme" consisted of the alleged misrepresentations and omissions discussed at length above. Because lead plaintiffs have failed to allege that KV and Hermelin engaged in a scheme or course of conduct distinct and independent from the alleged misrepresentations and omissions regarding KV's cGMP compliance and the Form 483s, the Court will dismiss lead plaintiffs' Rule 10b-5(a) and (c) claims against KV and Hermelin.

2. Lead Plaintiffs' Rule 10b-5(a) and (c) Claims Against Van Vliet and Bleser

In their amended complaint, lead plaintiffs claim that Van Vliet and Bleser "employed devices, schemes, and artifices to defraud and engaged in acts, practices and a course of business which operated as a fraud and deceit upon Class members, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder." (Doc. #66, at 64, para. 164). Additionally, they alleged that Van Vliet and Bleser "engaged in transactions, practices and a course of conduct that operated as a fraud and deceit upon the purchasers of KV securities[,] employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct in an effort to assure investors of KV's value and performance and continued substantial growth." (Doc. #66, at 64, para. 166). However, lead plaintiffs fail to allege with sufficient particularity how the scheme operated and how Van Vliet and Bleser were actually

involved. As such, the Court finds that lead plaintiffs' conclusory allegations fail to state claims under Rule 10b-5(a) and (c) against Van Vliet and Bleser.

C. Section 20(a) Claim Against Hermelin, Van Vliet, and Bleser

Section 20(a) of the Act provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). The Eighth Circuit holds that "a [§] 20 claim is derivative and requires an underlying violation of the 1934 [Securities Exchange] Act." *In re* Hutchinson Tech., Inc. Sec. Litig., 536 F.3d 952, 961 (8th Cir. 2008) (citing Deviries v. Prudential-Bache Sec., Inc., 805 F.2d 326, 329 (8th Cir. 1986) (noting that the court held that plaintiff's "[§] 20 claim was derivative of his other 1934 Act claims, and without any underlying violation of the 1934 Act or any rule or regulation promulgated under its authority, [plaintiff] could not state a claim under Section 20.").

In this case, lead plaintiffs assert a § 20(a) claim against Hermelin, Van Vliet, and Bleser. Because lead plaintiffs have failed to plead with particularity § 10(b) and Rule 10b-5 claims against these individual defendants, the Court finds that lead plaintiffs cannot assert a claim under § 20(a) against them. The Court, therefore, will dismiss lead plaintiffs' § 20(a) claims against Hermelin, Van Vliet, and Bleser.

Accordingly,

IT IS HEREBY ORDERED that the motion of defendant David A. Van Vliet to dismiss lead plaintiffs' consolidated amended complaint [Doc. #91] is granted.

IT IS FURTHER ORDERED that the motion of defendant David A. Van Vliet for oral argument on his motion to dismiss [Doc. #93] is denied as moot.

IT IS FURTHER ORDERED that the motions of defendant Rita E. Bleser to dismiss lead plaintiffs' consolidated amended complaint [Doc. ##94, 106] are granted.

IT IS FURTHER ORDERED that the motion of defendant Rita E. Bleser for oral argument on her motion to dismiss [Doc. #103] is denied as moot.

IT IS FURTHER ORDERED that the motion of defendant Marc S. Hermelin to dismiss lead plaintiffs' consolidated amended complaint [Doc. #95] is granted.

IT IS FURTHER ORDERED that the motion of defendant Marc S. Hermelin for oral argument on his motion to dismiss [Doc. #97] is denied as moot.

IT IS FURTHER ORDERED that the motion of defendant KV Pharmaceutical Company to dismiss lead plaintiffs' consolidated amended complaint [Doc. #99] is granted.

IT IS FURTHER ORDERED that the motion of defendant KV Pharmaceutical Company for oral argument on its motion to dismiss [Doc. #98] is denied as moot.

IT IS FURTHER ORDERED that lead plaintiffs' motion to lift the stay of discovery [Doc. #74] is denied as moot.

CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

Dated this 22nd day of February, 2010.